Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:

Transcatheter Mitral Valve Repair (TMVR)

Effective: January 1, 2026

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request to the FAX numbers below	Yes ☐ No ☒
Notification Required IF REQUIRED, concurrent review may apply	Yes ☐ No ☒

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; 800-232-0816
☒ Tufts Health Plan Commercial products; 617-972-9409

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055
☒ Tufts Health Together – MassHealth Accountable Care Partnership Plans; 888-415-9055
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404
☒ Tufts Health One Care – A dual-eligible product; 857-304-6304

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-972-9409
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-972-9409
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-972-9409

Note: While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

Overview

The Plan may cover FDA approved mitral valve system for Members who meet specific guidelines. Mitral regurgitation (MR) is a backflow of blood from the left ventricle to the left atrium due to mitral valve insufficiency. Transcatheter mitral valve repair is sometimes recommended for primary mitral valve disease (MVD) e.g., degenerative mitral regurgitation (DMR), which is usually due to direct damage or wear of the MV leaflets, attached chords, or adjacent supporting tissues. The procedure involves clipping together a portion of the mitral valve leaflets as a treatment for reducing MR with the intended outcome to improve recovery of the heart from overwork, improve function, and potentially halt the progression of heart failure.

Clinical Guideline Coverage Criteria

The Plan considers elective transcatheter mitral valve repair (TMVR) as reasonable and medically necessary when **one** of the following is met:

1. The Member has significant primary (degenerative) mitral regurgitation (MR ≥ 3+); and **all** of the following**:**
    a. The Member remains severely symptomatic in spite of optimal medical management and recommends an interventional procedure; **and**
    b. A cardiothoracic surgeon has documented the Member has a **prohibitive risk for an open mitral valve operation; **or**

2. The Member has heart failure with secondary moderate-to-severe or severe MR (MR ≥ Grade III) per American Society of Echocardiography criteria and **all** of the following:
    a. The member remains symptomatic despite guideline directed medical therapy (GDMT); **and**
    b. Left Ventricular Ejection Fraction (LVEF) ≥ 20% and ≤ 50%; **and**
    c. Left Ventricular End-Systolic Diameter (LVESD) ≤ 70mm

*New York Heart Association Classification System[7]

Functional Capacity	Objective Assessment
Class I. Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.	**A.** No objective evidence of cardiovascular disease.
Class II. Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.	**B**. Objective evidence of minimal cardiovascular disease.
Class III. Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.	**C.** Objective evidence of moderately severe cardiovascular disease.
Class IV. Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.	**D.** Objective evidence of severe cardiovascular disease.

** Prohibitive risk is defined by any one of the following criteria[9]:

- Severe pulmonary hypertension (systolic pulmonary artery pressure >2/3 systemic pressure)
- Unusual extenuating circumstance, such as right ventricular dysfunction with severe tricuspid regurgitation, chemotherapy for malignancy, major bleeding diathesis, immobility, AIDS, severe dementia, high risk of aspiration, internal mammary artery at high risk of injury, etc.
- 30-day STS predicted operative mortality risk score of:
    - ≥ 8% (mitral valve replacement)
    - ≥ 6% (mitral valve repair)
- Porcelain aorta or extensively calcified ascending aorta
- Frailty (assessed by in-person cardiac surgeon consultation)
- Hostile chest
- Severe liver disease / cirrhosis (MELD Score >12)

***Moderate to severe or severe MR may be determined by:

- Grade 3+ (moderate) or 4+ (severe) MR confirmed by echocardiography
- New York Heart Association (NYHA) functional class II, III, or IVa (ambulatory) despite the use of stable maximal doses of guideline-directed medical therapy and cardiac resynchronization therapy (if appropriate) administered in accordance with guidelines of professional societies.

Limitations

The Plan does not cover TMVR for any the following:

1. Members who cannot tolerate, including allergy or hypersensitivity to, procedural anticoagulation or post procedural anti-platelet regimen.
2. Members with known hypersensitivity to clip components (nickel / titanium, cobalt, chromium, polyester), or with contrast sensitivity.
3. Active endocarditis of the mitral valve,
4. Rheumatic mitral valve disease,
5. Evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus.
6. Members with any other contraindication to TMVR.

Codes

The following code(s) are associated with this service:

Table 1: CPT/HCPCS Codes

Code	Description
33418	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis
33419	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; additional prosthesis(es) during same session (List separately in addition to code for primary procedure)
0345T	Transcatheter mitral valve repair percutaneous approach via the coronary sinus

References:

1. Center for Medicare and Medicaid Services (CMS). Proposed Decision Memo for Transcatheter Mitral Valve (TMV) Procedures (CAG-00438N) 2014. Available online at: cms.gov/medicarecoverage-database/details/nca-proposed-decision-memo.aspx?NCAId=273. Accessed October 6, 2021.
2. FDA. Summary of Safety and Effectiveness Data: Mitral Valve Repair Device. 2013. Available online at: accessdata.fda.gov/cdrh_docs/pdf10/P100009b.pdf.
3. Feldman T., Foster E., Glower D.D., et al; Percutaneous repair or surgery for mitral regurgitation. N Engl J Med. 2011;364:1395-1406.
4. Hayes Inc. Hayes Medical Technology Directory. Percutaneous mitral valve repair. February 20, 2014. Lansdale, PA: Hayes, Inc.; Updated February 25, 2015.
5. Lim DS, Reynolds MR, Feldman T, et al. Improved functional status and quality of life in prohibitive surgical risk patients with degenerative mitral regurgitation following transcatheter mitral valve repair with the MitraClip(R) system. J Am Coll Cardiol 2013.
6. Nishimura RA, Otto CM, Bonow RO et al. 2014 AHA/ACC Guideline for the management of patients with valvular heart disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation 2014; 129(23):2440-92.
7. The Criteria Committee of the New York Heart Association. Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels. 9th ed. Boston, Mass: Little, Brown & Co; 1994:253-256.
8. Whitlow P.L., Feldman T., Pedersen W.R., et al; Acute and 12–month results with catheterbased mitral valve leaflet repair: the EVEREST II (Endovascular Valve Edge-to-Edge Repair) High Risk Study. J Am Coll Cardiol. 2012;59:130-139
9. **Abbott.** *MitraClip Patient Selection Criteria Guide*. Abbott, 2021. Available at: https://mitraclip.com/physician/fileadmin/Downloads/50433_MitraClip_Patient_Selection_Criteria_Guide.pdf. Accessed November 5, 2024.

Approval And Revision History

November 18, 2020: Reviewed by the Medical Policy Approval Committee (MPAC), renewed without changes

Subsequent endorsement date(s) and changes made:

- December 8, 2020: Fax number for Unify updated
- October 20, 2021: Reviewed by IMPAC, PA status changed to No PA required, effective October 20, 2021
- October 19, 2022: Reviewed by MPAC, renewed without changes for integration between Harvard Pilgrim Health Care and Tufts Health Plan
- November 16, 2023: Reviewed by MPAC, renewed without changes
- November 2023: Unify name changed to One Care, effective January 1, 2024
- November 21, 2024, Reviewed by MPAC, Update to limitations based on manufacturer label. Added definition of “Prohibitive Risk” and “Moderate to Severe Mitral Regurgitation” to the Medical Necessity Guideline (MNG). Effective January 1, 2025
- December 13, 2024: Reviewed and approved by the UM Committee effective January 1, 2025
- November 19, 2025: Reviewed by MPAC for annual review, renewed without changes effective January 1, 2026
- December 2025: Administrative updates effective January 1, 2026
- December 8, 2025: Reviewed by UM Committee for annual review, renewed without changes effective January 1, 2026

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis

considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.